was developed in UK English (Speight and Bradley; 2001) and most recently updated in 2008 in consultation with UK diabetologists, a diabetes specialist nurse (DSN), a dietician, and a podiatrist. A conceptual definition of each item was provided by the developer, forward translations were produced in Germany and Spain. Results of the first translations and questions were discussed with the developer and a diabetologist, DSN, dietician and the translation team in each country. The initial UK version was revised. The German and Spanish versions were back translated into UK English and tested for acceptability and comprehension during cognitive debriefing interviews with eight people with diabetes in each country, before final language versions were established. **RESULTS:** First results obtained after the forward translation and discussion in Spain and Germany showed that diabetes management differs somewhat across countries and differences in dietary habits and alcohol use necessitated some adaptation to the questions. The establishment of a harmonized questionnaire required some rewording of items and reordering. Challenges encountered, including those concerning diet and alcohol, and how these were dealt with during all steps of the process will be described in the presentation. **CONCLUSIONS:** An internationally acceptable version of the ADKnowl was developed following a rigorous methodology to facilitate international comparison and pooling of data. This project demonstrates the importance of assessing the suitability of the item content of a knowledge measure to the clinical and cultural context of the target countries.

PDB56

THE IMPACT OF STARTING INSULIN GLARGINE VERSUS INSULIN DETEMIR ON QUALITY OF LIFE (QOL) AND TREATMENT SATISFACTION (TS) IN PATIENTS WITH TYPE 2 DIABETES INADEQUATELY CONTROLLED ON ORAL GLUCOSE-LOWERING DRUGS (OGLDS)

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OBJECTIVES: To compare the impact of starting either insulin glargine once-daily or insulin detemir twice-daily on multiple dimensions of QOL in patients with type 2 diabetes inadequately controlled on OGLDs. **METHODS:** This study was part of a 24-week, multinational, randomised trial in which 964 insulin-naïve patients, aged 40–75 years, with inadequately controlled type 2 diabetes (HbA1c 7.0–10.5%) were randomised to glargine once-daily or detemir twice-daily. For both insulins the dose was titrated every 2 days by 2 U to obtain fasting plasma glucose <5.6 mmol/l. For detemir, there also was a pre-dinner target <5.6 mmol/l. QOL and TS were assessed using: type 2 Diabetes Symptom Checklist revised (DSC-r), World Health Organization-5 well-being index (WHO-5), Hypoglycaemia Fear Survey (HFS) and Diabetes Treatment Satisfaction Questionnaire (DTSQ). Higher scores indicate greater symptom distress, well-being, worries about hypoglycaemia and TS, respectively. Data were analysed using ANCOVA. **RESULTS:** HbA1c reductions and overall hypoglycaemia were comparable between glargine and detemir (mean ± SD change in HbA1c: −1.46 ± 1.09 and −1.54 ± 1.11%, respectively [P = 0.149]). Total diabetes-related symptom distress (DSC-r) decreased in both treatment groups. There were no significant differences between groups, except for the neuropathic pain subscale (P = 0.027 in favour of glargine). Well-being (WHO-5) increased equally in both groups (+6.13 ± 21.47 for glargine and +7.54 ± 19.06 for detemir on scale 0–100, P = 0.742). There was no significant difference between treatments for the HFS (P = 0.441). TS (DTSQ) improved for both treatment groups, but significantly more for glargine than for detemir: Mean ± SD increase in total satisfaction score (scale 0–36): 5.1 ± 8.6 for glargine and 4.1 ± 8.8 for detemir (P < 0.001). **CONCLUSIONS:** Initiating glargine once-daily or detemir twice-daily in patients with type 2 diabetes failing OGLDs resulted in similarly improved glycaemic control, associated with an overall positive effect on diabetes symptom distress and emotional well-being. TS improved with both insulins, however, improvement was significantly greater with glargine than detemir.

PDB57

COMPARING THE IMPACT OF DEPRESSION, DIABETES, AND ANXIETY ON PATIENT PRODUCTIVITY AND QUALITY OF LIFE: RESULTS FROM A NATIONALLY REPRESENTATIVE PANEL DATA

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OBJECTIVES: This study aims to estimate and compare quality of life and productivity loss among three chronic and prevalent conditions. **METHODS:** Retrospective secondary database analysis using Medical Expenditure Panel Survey data from years 2000–2003 was conducted. Patients identified using the 3-digit ICD-9 codes: diabetes(250) depression(311) and anxiety(300). QOL was measured using EQ-5D & productivity measured using absenteeism data. **RESULTS:** A total of 12,858 patients were identified, 11% of patients had two or more of the conditions studied. About 17% of diabetes patients had an EQ-5D index score of <0.30, compared to 20% each on depression and anxiety. All 3 conditions had significant impact on patient's overall QOL (p < 0.001). Mean EQ 5D index for diabetes was 0.65 (95% CI 0.64–0.66), depression—0.62 (95% CI 0.61–0.63), and anxiety—0.62 (95% CI 0.61–0.64). More number of patients with depression and anxiety missed work (21%) and stayed in bed (17%) due to illness compared to diabetes patients (12% and 9% respectively), but the mean days diabetes patients missed work was higher—12.15 (95% CI 10.38–13.92) compared to anxiety—9.39 (95% CI 7.8–10.89) and depression—8.88 (95% CI 7.79–9.96) **CONCLUSIONS:** All three conditions were found to have a significant negative impact on patient's QoL and productivity. Our research indicates that anxiety and depression inflict similar disease burden compared to diabetes on patient. Future research should focus on reducing this burden.

DIABETES/ENDOCRINE DISORDERS – Health Care Use & Policy Studies

PDB58

THE "WHO, HOW AND THEN WHAT…" OF INSULIN INITIATION IN UK PRIMARY CARE

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OBJECTIVES: To understand how insulin is initiated, describe patients with type 2 diabetes (T2DM) initiating insulin in UK primary care, and look at changes in therapy, clinical outcomes and contact with health care professionals (HCPs) after insulin initiation. **METHODS:** Patients aged ≥18 years with a code for T2DM initiating insulin (baseline) from May 2004 to May 2006 were identified in the THIN database. Patient characteristics, clinical measures, treatment and contact with HCPs were collected at baseline and during 6 months follow-up. **RESULTS:** A total of 4045 patients met the inclusion criteria, 56% were male. Patient characteristics at baseline [mean (SD)] were; age: 62.6(13.3) years, BMI: 30.2(6.5) kg/m^2 and HbA_{1c}: 9.6%(2.0%). The most prevalent co-morbidities were hypertension (63%), coronary heart disease (26%), hyperlipaedemia (24%), and depression (22%). 97.4% of patients had contact with their GP-surgery in the 6 months before insulin initiation, mean 7.1 contacts; 78.1% were referred to secondary care; and 18% were hospitalised. In the 12 months prior to insulin initiation 8.5% of patients had no prescriptions for oral antidiabetic medications (OAD), 13.4% for a single OAD class and 78.1% for ≥2 different OAD classes. 52.4% of patients initiated intermediate/long acting insulin therapy only, a further 41.6% pre-mix insulin only and the remainder initiated basal bolus (4.0%) or fast acting only (2.1%). During follow-up, 14.7% discontinued insulin therapy, 6.8% switched to a different regimen and 4.7% intensified therapy; adding mealtime insulin. Of the patients with a measurement during follow-up (n = 3024), 17.3% achieved target HbA_{1c} (<7%). Clinical outcomes during follow-up [mean (SD)] were; HbA_{1c}: 8.3 (1.6)% and BMI: 30.7 (6.6) kg/m^2. There was a slight increase in contact with HCPs during follow-up, mean 8.5 GP-surgery contacts. **CONCLUSIONS:** Patients had elevated HbA_{1c} at insulin initiation, simple regimens were favoured; during a 6 month follow-up a high proportion of patients failed to achieve glycaemic target.

PDB59

USING THE ECHO MODEL TO EXAMINE THE EFFECT OF AN EMPLOYER-SPONSORED PHARMACIST PROVIDED DIABETES MTM PROGRAM ON OUTCOMES

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OBJECTIVES: To examine economic, clinical, and humanistic outcomes of a pharmacist-provided Medication Therapy Management (MTM) program. **METHODS:** One year prospective, pre-post longitudinal study. Employees and dependents with a diagnosis of Type 2 diabetes were included. Pharmacists provided MTM services at 7 community pharmacies on five occasions in one year. Data collected: economic outcomes included costs and numbers of ER visits hospitalizations etc., clinical (A1C, blood pressure etc.), social (caffeine intake, alcohol consumption etc.), and process measures (podiatrist visits, eye exams, etc.), humanistic (patient's quality of life (SF-36), medication adherence etc.). Data was analyzed using SPSS v. 16.0. Descriptive statistics, Wilcoxon signed-rank tests and Friedman tests were used. Data analyses for the period between baseline and 6 month is given below. **RESULTS:** Ninety five patients enrolled at baseline. Mean A1c improved from 8.02 to 7.67 (p = 0.20). Patients with uncontrolled A1cs at baseline saw a significant decrease toward goal at six months. (p = 0.01). Systolic blood pressure improved from 136.00 to 131.94 mmHg (p = 0.221) and improved significantly for patients with baseline SBP ≥ 140 (p = 0.000). Patients satisfaction (p = 0.000) and adherence improved from baseline (p = 0.015). Quality of life scores improved but these changes were not significant. Visits to specialty physicians improved significantly from the previous year. On average, physician office visits reduced from 10.2 to 8.36. Number and costs for ER visits decreased. Average hospitalization costs decreased from $ 22,252.24 to $ 17,016.19 and length of stay decreased by approximately 1.4 days. Total costs decreased by 62.69% (~$200,000). **CONCLUSIONS:** This MTM program has demonstrated improved outcomes and cost savings within the first six months. Final results for the one year time point will be presented.

PDB60

EVALUATION OF THE PATIENT'S PERSPECTIVE OF MEDICAL CARE IN TYPE 2 DIABETES DISEASE MANAGEMENT PROGRAMS

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OBJECTIVES: Diabetes disease management programmes (DDMP) were introduced in German statutory health insurance companies to improve medical care by funding health care based on evidence-based medical guidelines. The aim of this study was to compare persons with type 2 diabetes (DM2s) enrolled in a DDMP to those not enrolled regarding quality of health care and medical endpoints. **METHODS:** A population based follow-up study was performed by the Cooperative Health Research in the Region of Augsburg (KORA) between 2006 and 2008. All DM2s received a

questionnaire regarding their medical care and self management. Medications (within the last 7 days), physical examination and laboratory tests were documented. DDMP participation was validated by the primary physician. Only DM2s with statutory health insurance and validated DDMP enrolment were included in the analysis (n = 166). Regression analyses adjusting for confounders (age, sex, education, diabetes duration and previous diabetes complications) were conducted. **RESULTS:** DDMP enrolees (n = 89) reported medical examination of eyes and feet and medical advice regarding diet and physical activity more frequently ($p < 0.005$), received antidiabetic and antihypertensive medications more often ($p < 0.05$) and attended diabetes education more frequently ($p < 0.005$). DDMP enrolees measured their blood pressure more frequently ($p < 0.05$). The groups did not differ regarding Hemoglobin A1c (HbA1c), but of 54 DM2s with values over 7%, only 3.6% of DDMP enrolees were receiving no antihyperglycemic medication whereas this was true for 38.5% of those not in DDMP. This difference remained significant ($p = 0.0129$) after adjustment for diabetes duration. **CONCLUSIONS:** According to our study, health care quality in DDMPs is improved. However, patient self-management of all diabetics must be improved.

PDB61

DIABETES REGIMEN UTILIZATION IN A LARGE MANAGED CARE SETTING; A COMPARISON WITH ADA/EASD CONSENSUS STATEMENT GUIDELINES

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OBJECTIVES: Diabetes extracts a considerable economic toll on the US health care system. An analysis conducted in 2007, indicated that the economic burden of diabetes was $174 billion, with direct medical expenditures accounting for $116 billion. Originally published in 2006 and updated yearly, the American Diabetes Association (ADA)/European Association for the Study of Diabetes (EASD) Consensus Algorithm for the Initiation and Adjustment of Therapy, stands to guide health care practitioners in determining the most appropriate lifestyle and pharmacotherapeutic interventions for patients with Type 2 diabetes. We conducted an analysis to compare medication regimens from claims adjudicated by patients with Type 2 diabetes to treatment regimens outlined in the ADA/EASD guidelines. **METHODS:** This retrospective claims analysis utilized data from the 2007 MarketScan® Commercial Claims and Encounters and the Medicare Supplemental and Coordination of Benefits databases from Thomson Reuters. Medication regimens were evaluated for patients with Type-2 diabetes and at least one prescription claim for the fourth quarter of 2007. In order to be considered as part of a treatment regimen all medications must have had an overlapping 45 day period of utilization in the quarter. All identified medication regimens were compared to 2008 ADA/EASD consensus guidelines **RESULTS:** A total of 191,535 patients were included in the analysis. In rank order, the top five treatment regimens by utilization frequency were as follows: biguanide monotherapy (27.9%), sulfonylurea monotherapy (14.53%), sulfonylurea+biguanide combination therapy (12.01%), thiazolidinedione monotherapy (9.21%), thiazolidinedione+biguanide combination therapy (6.97%). **CONCLUSIONS:** As expected, following ADA/EASD guidelines, monotherapy with biguanide and a regimen of biguanide+sulfoylurea were among the most frequently utilized regimens. The high degree of sulfonylurea monotherapy utilization may suggest that many patients may not tolerate monotherapy with biguanide. In all cases treatment must be individualized requiring the use of other agents to control blood glucose levels.

PDB62

ECONOMIC IMPACT OF COMPLIANCE AND PERSISTENCE TO TREATMENT WITH ANTIDIABETES MEDICATION IN T2DM—A SYSTEMATIC REVIEW

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OBJECTIVES: Suboptimal compliance and failure to persist with antidiabetes therapies are of potential economic significance. The present research aims to review the recent literature regarding the impact of poor compliance and persistence with antidiabetes medications on the cost of health care or its components for patients with type 2 diabetes mellitus (T2DM). **METHODS:** Systematic literature search was conducted in pubmed for relevant articles published in the period between January 1, 2000 and April 30, 2009. Studies describing economic consequence of compliance and/or persistence with pharmaceutical antidiabetes treatment were identified. **RESULTS:** Of 449 articles corresponding to the primary search algorithm, 12 studies (all conducted in USA) fulfilled inclusion criteria regarding the economic impact of compliance and/or persistence with treatment on the overall cost of T2DM care or its components. Compliance was assessed via medication possession ratio (MPR) in 10 studies, and ranged from 0.52 to 0.93 depending on regimen. Persistence was assessed in one study. Mean total annual costs per patient having T2DM varied between the studies, ranging from $4,570 to $17,338. In 7 studies medication compliance was inversely associated with total health care costs, while in four other studies inverse associations between medication compliance and hospitalisation costs were reported. In one study increased adherence did not change overall health care costs. **CONCLUSIONS:** Improved compliance can lead to reductions of the total health care costs in T2DM, mainly through decrease in hospitalisations. Studies assessing economic impact of persistence with pharmacotherapy in T2DM are limited, and studies investigating cost consequences of compliance are predominantly using MPR as a measure of compliance. Further research is needed in countries other than USA to assess impact of compliance and persistence to pharmacotherapy on T2DM costs in country-specific settings. Researchers should follow definitions of compliance and persistence proposed by the ISPOR Medication Compliance and Persistence Special Interest Group.

PDB63

THE UTILIZATION OF ROSIGLITAZONE AND PIOGLITAZONE AFTER THE CARDIOVASCULAR RISK-WARNINGS: WAS THERE A DIFFERENTIAL EFFECT?

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OBJECTIVES: Meta-Analyses of oral hypoglycemic agents (OHA) revealed that Rosiglitazone (Rosi) increased the risk of Myocardial Infarction (MI) and Heart Failure (HF), and Pioglitazone (Pio) increased the risk of HF and decreased the risk of MI. The objective of this research is to compare OHA utilization patterns, before and after these publications. **METHODS:** CareFirst BlueCross BlueShield's claims were analyzed for patients continuously enrolled from January 2005 through December 2007 who started on mono-Rosi or mono-Pio. The "pre-publication" period (November 1, 2006—March 31, 2007) was compared to the "post-publication" period (July 1, 2007—December 1, 2007) using a difference-in-difference approach. Multinomial logistic regression (MLR) explored discontinuation; continuation with monotherapy or adding another drug; and switching after adjusting for gender, age, type of insurance, history of MI or HF and risk factors for MI and HF. **RESULTS:** The number of monotherapy Rosi users decreased from the pre (N = 368, 5.94%) to post (N = 170, 2.87%) period, while monotherapy Pio use was stable across the two periods. The proportion who switched from Rosi to non-Rosi drugs changed from 2.17% in pre-period to 5.88% in post period. Adjusted relative risk was 2.66 (95 % CI 1.0569, 6.7689). Pio to non-pio drugs switching was 1.48% in pre-period and 1.16% in post-period (relative risk not significant). Therefore, the impact of the new studies on Rosi users to switch to non-Rosi drug, relative to Pio users before and after the publication was 3.6189 (90%CI 1.051, 12.457). **CONCLUSIONS:** Consistent with prior research, the utilization of Rosi declined by more than half in the post-period. Additionally, Rosi users were three times more likely to switch to a non-Rosi drug in the post period, relative to Pio users. Therefore, our results show that the publications about safety risks had differential impact between the two drugs within therapeutic class.

PDB64

A RETROSPECTIVE DATABASE ANALYSIS OF PERSISTENCE WITH INSULIN IN PATIENTS WITH TYPE 2 DIABETES ADDING MEALTIME INSULIN TO A BASAL REGIMEN

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OBJECTIVES: Following a commitment to an intensive glucose-lowering regimen that includes mealtime insulin is eventually required by patients taking basal insulin to maintain good glycemic control. The objective of this study was to characterize and examine factors associated with persistence to mealtime insulin. **METHODS:** Patients with diagnosed type-2 diabetes, with at least 2 prescriptions for mealtime insulin (index medication) between July 2001 and Sept 2006, were identified from a US managed care claims database. Patients were required to have 6 months pre- and 15 months post-index continuous eligibility and at least 2 basal insulin prescriptions in pre-index period. Persistence measure #1 was defined by the absence of prescription gap of greater than 90 days, with non-persistence effective the date of the last prescription prior to the 90 day gap. Persistence measure #2 required one prescription per quarter to be persistent at 12 months; persistence at 3 and 6 months were defined similarly. Logistic regression models were used to examine predictors of persistence to mealtime insulin at 12 months. **RESULTS:** Patients adding mealtime insulin to their basal regimen (n = 4,752; 51% male, mean age = 60.3 years) mostly used insulin analogs (60%) and vial/syringe (87%). The median number of mealtime insulin prescription claims filled per patient was 2, 3 and 4 at 3, 6 and 12 months respectively, with the median time between refills being 75.5 days. Persistence to mealtime insulin was 40.7%, 30.2% and 19.1% using measure #1 and 74.3%, 55.3% and 42.2% using measure # 2 at 3, 6 and 12 months, respectively. Patients initiating with human insulin were less likely to be persistent across measures of persistence ($OR < 0.80$, $p < 0.01$). Additional predictors of persistence at 12 months included age, copayment, mental health comorbidity and polypharmacy. **CONCLUSIONS:** Persistence to insulin therapy is poorer than one would anticipate and is significantly lower for human insulin compared to analogs.

PDB65

REAL-LIFE PRESCRIPTION PATTERNS SHOW FEWER TREATMENT CHANGES WITH BASAL INSULIN ANALOGS COMPARED TO NPH IN TYPE 2 DIABETES IN THE NETHERLANDS

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OBJECTIVES: Using the Dutch PHARMO database, the aim was to 1) determine the percentage of type 2 diabetes (T2D) patients starting on long-acting insulin analogues versus NPH; 2) compare previous insulin experience in patients; and 3) establish the number of patients changing treatment within one year. **METHODS:** The PHARMO database includes community pharmacy drug dispensing and hospitalisation records